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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,012	09/14/2001	Colin Gerald Caro	BKY2-0074	7764

7590 01/22/2007
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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/857,012

Applicant(s)

CARO ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,6,12-16,24-31,44 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,6,12-16,24-27,44 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Upon further consideration and consultation with another examiner, the Examiner concluded that the present claims are not patentable over the prior art. The indicated allowability of the claims has been withdrawn. The Examiner regrets any inconvenience that this action may cause the Applicant.

Election/Restrictions

Claims 28-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 1, 2003.

Claims 28-31 are not drawn to the elected species of Figures 6a to 6c but appear to be drawn to the species of Figure 1a, 1c, and 7-12; these claims have been withdrawn in order to reduce the number of issues for prosecution.

Claim Objections

Claims 44, 47, and 49 are objected to because of the following informalities:

On lines 2 to 3 of claim 44, the language "portion which supports an interior wall of the vessel and imposes a shape thereon" appears to positively claim a part of a living organism (i.e. an interior wall of the vessel). The Examiner suggests changing the word "supports" to ---is capable of supporting---, and to change "imposes" to ---is capable of imposing--- in order to overcome this objection.

On line 2, claim 47, the language "tube which supports an interior wall of the vessel" appears to positively claim a part of a living organism (i.e. an interior wall of the

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vessel). The Examiner suggests changing the word "supports" to ---is capable of supporting--- in order to overcome this objection.

On lines 3 to 5 of claim 49, the serial clauses thereof make the language confusing. The Examiner suggests changing these lines to read:

---a hollow tube including a plurality of openings located in a wall thereof such that an interior wall of the vessel is capable of being exposed to fluid flow along the vessel when inserted into the vessel; the hollow tube is capable of supporting the interior wall of the vessel, and---

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 6, 24-25, 27, 44, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 95/09585) in view of Simon et al (US 5,354,308) or Fontaine (US 5,443,498). Caro discloses a vascular prosthesis that includes tubing that can include an internally inserted stent to give it a non planar curvature that induces swirl flow; see Figures 5 to 8 and page 5, line 28 to page 6, line 30. Ideally, prostheses tubing, such as tubing or graft 1 of Caro, are designed to be like blood vessels. A stent is inserted therein in order keep the tubing open and to prevent it from collapsing or kinking; see page 6, lines 6-10. The member (8) can even be inserted into a blood

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vessel in order to receive flow therefrom; see page 6, lines 24-30. The internally inserted stent of Caro is clearly capable of imposing the non planar shape on the tubing, and therefore, it inherently or at least obviously is capable of imposing such a shape on a blood vessel. It is not clear whether the stent of Caro has opening therein as claimed.

Claims 3, 5, 6, 24-27, 44, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 95/09585) in view of Simon et al (US 5,354,308). Caro discloses a vascular prosthesis that includes tubing that can include an internally inserted stent to give it a non planar curvature that induces swirl flow; see Figures 5 to 8 and page 5, line 28 to page 6, line 30. Ideally, prostheses tubing, such as tubing or graft 1 of Caro, are designed to be like natural healthy blood vessels in that they are replacements thereof. A stent is inserted therein in order keep the tubing open and to prevent it from collapsing or kinking; see page 6, lines 6-10. The member (8) can even be inserted into a blood vessel in order to receive flow therefrom; see page 6, lines 24-30. The internally inserted stent of Caro is clearly capable of imposing the non planar shape on the tubing, and therefore, it inherently or at least obviously is capable of imposing such a shape on a blood vessel. It is not clear whether the stent of Caro has opening therein as claimed.

However, Simon teaches that it was known to art to make stent with openings in the walls thereof; see Simon on the front page and in Figures 8 and 9. Therefore, it is the Examiner's position that it would have been obvious to utilize the stents of Simon as the stent of Caro for the same reasons that Simon utilizes the same within vessels or grafts.

With regard to claim 26, Simon teaches that the stent thereof can be made with shape memory alloy; see column 3, line 61 et seq.

Claims 12-16 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro, Simon, and Fontaine as applied to claims 3, 5, 6, 24, 25, 27, 44, and 47-49 above, and further in view of Schwartz et al (6,015,387). Caro fails to disclose the monitoring device as claimed. However, Schwartz teaches that such devices were known to the art at the time of the invention; see the abstract and figures. Therefore, it would have been obvious to include a monitoring device in the Caro device for the same reasons that Schwartz uses the same and in order to monitor the blood to see if the swirl flow desired is occurring.

With regard to claims 14 and 15, the Schwartz sensor is electrically connected to the power supply and it electromagnetically transmits a signal to a remote monitor, which must have a power supply and recording means to function. This is necessary because the monitor performs a calculation and displays a result; see column 2, lines 25-36. The monitor of Schwartz also uses ultrasound to detect blood flow; see *supra*.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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